## **CLAIMS**

## **Composition Claims**

- 1.) A coated stent comprising:
  - a) a stent and
  - b) a coating composition comprising:
    - 1) an HMG-CoA reductase inhibitor in an amount effective to inhibit proliferation of smooth muscle cells in a body lumen of a patient, and
    - 2) a carrier.
- 2. The coated stent of claim 1 wherein the carrier is a nonpolymeric carrier.
- 3. The coated stent of claim 1 wherein the carrier is a polymeric carrier.
- 4. The coated stent of claim 1 wherein the carrier is a liquid at body temperature.
- 5. The coated stent of claim 4 wherein the carrier is a solid at room temperature.
- 6. The coated stent of claim 1 wherein the carrier is polymeric and the HMG-CoA reductase inhibitor is physically bound to the carrier.
- 7. The coated stent of claim 1 wherein the carrier is polymeric and the HMG-CoA reductase inhibitor is chemically bound to the carrier.
- 8. The coated stent of claim 1 wherein the coating composition is a liquid at body temperature.
- 9. The coated stent of claim 8 wherein the coating composition is a solid at room temperature.
- 10. The coated stent of claim 1 wherein the coating composition further comprises:
  - a. a solvent and wherein the coating composition is a liquid at body temperature.
- 11. The coated stent of claim 1 wherein the coating composition is a solid at body temperature.
- 12. The coated stent of claim 1 wherein the coating composition comprises from about 1 wt% to about 50 wt% HMG-CoA reductase inhibitor, based on the total weight of the coating composition.
- 13. The coated stent of claim 1 wherein the coating composition comprises from about 5 wt% to about 30 wt% HMG-CoA reductase inhibitor, based on the total weight of the coating composition.

- 14. The coated stent of claim 1 wherein the coating composition comprises from about 10 wt% to about 20 wt% HMG-CoA reductase inhibitor, based on the total weight of the coating composition.
- 15. The coated stent of claim 1 wherein the HMG-CoA reductase inhibitor is selected from the group consisting of cerivastatin, atorvastatin, simvastatin, fluvastatin, lovastatin, and pravastatin.
- 16. The coated stent of claim 1 wherein the HMG-CoA reductase inhibitor is cerivastatin.

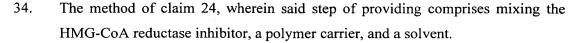
The coated stent of claim 1 wherein the coating composition further comprises:

- a) a restenosis inhibitor which is not an HMG-CoA reductase inhibitor.
- 18. The coated stent of claim 1 wherein the carrier is non-reactive with the HMG-CoA reductase inhibitor.
- 19. The coated stent of claim 1 wherein the carrier comprises a polymer having no functional group that is reactive with the HMG-CoA reductase inhibitor.
- 20. The coated stent of claim 1 wherein the carrier comprises a biodegradable polymer.
- 21. The coated stent of claim 1 wherein the carrier comprises a polymer selected from the group consisting of polyhydroxy acids, polyanhydrides, polyphosphazenes, polyalkylene oxalates, biodegradable polyamides, polyorthoesters, polyphosphoesters, polyorthocarbonates, and blends or copolymers thereof.
- 22. The coated stent of claim 1 wherein the carrier comprises a biostable polymer.
- 23. The coated stent of claim 1 wherein the carrier comprises a polymer selected from the group consisting of polyurethanes, silicones, acrylates, polyesters, polyalkylene oxides, polyalcohols, polyolefins, polyvinyl chlorides, cellulose and its derivatives, fluorinated polymers, biostable polyamides, and blends or copolymers thereof.
- 24. A method of coating a stent comprising:
  - a) providing a stent;
  - b) providing a coating composition comprising

SBI-082

- 1) an HMG-CoA reductase inhibitor in an amount effective to inhibit proliferation of smooth muscle cells in a body lumen of a patient; and
- 2) a carrier; and
- c) applying the coating composition to the stent.
- 25. The method of claim 24, wherein said step of providing the coating composition comprises mixing the HMG-CoA reductase inhibitor, the carrier, and a solvent under conditions such that the HMG-CoA reductase inhibitor does not chemically react to any substantial degree with the carrier.
- 26. The method of claim 24, wherein said step of providing the coating composition comprises mixing the HMG-CoA reductase inhibitor, the carrier, and a solvent at a temperature of from about 20°C to about 30°C.
- 27. The method of claim 24, further comprising:
  - expanding the stent before applying the coating composition to the stent.
- 28. The method of claim 24, wherein said step of applying comprises spraying the coating composition onto the stent.
- 29. The method of claim 24, wherein said step of applying comprises immersing the stent in the coating composition.
- 30. The method of claim 24, further comprising:
  - a) drying the stent after the coating composition is applied to the stent.
- 31. The method of claim 24, wherein said step of providing comprises forming the coating composition into a film, and said step of applying comprises wrapping the film around the stent.
- 32. The method of claim 24, further comprising:
  - a) drying the stent after the coating composition is applied to the stent and
  - b) applying a second coating composition comprising a polymer to the dried stent.
- 33. The method of claim 24, further comprising:
  - a) drying the stent after the coating composition is applied to the stent; and
  - b) applying a second coating composition comprising a polymer and a substantially unreacted HMG-CoA reductase inhibitor to the dried stent.

SBI-082



- 35. The method of claim 24, wherein said step of providing comprises providing said HMG-CoA reductase inhibitor at from about 1 wt% to about 50 wt%, based on the total weight of the coating composition.
- 36. The method of claim 24, wherein the carrier is nonreactive with the HMG-CoA reductase inhibitor.
- 37. The method of claim 24, wherein the carrier comprises a biodegradable polymer.
- 38. The method of claim 24, wherein the polymer includes a biostable polymer.
- 39. The method of claim 24, wherein the HMG-CoA reductase inhibitor is selected from the group consisting of cerivastatin, atorvastatin, simvastatin, fluvastatin, lovastatin, and pravastatin.
- 40. The method of claim 24, wherein the HMG-CoA reductase inhibitor is cerivastatin.
- 41. A method of treating restenosis, comprising
  - a) providing a coated stent comprising
    - 1) a stent, and
    - a coating composition, coupled to said stent, comprising an HMG-CoA reductase inhibitor and a carrier,
  - b) delivering said coating stent to an occluded body lumen, and
  - c) expanding said stent to provide support to said body lumen.

5